

**REMARKS**

Claim 14 has been amended so that it is in independent form and also to limit the recitations for Ra. Claim 15 has been amended to be consistent with amended claim 14. Claims 16 and 18-24 have been amended so that they depend from claim 14. Claim 17 has been canceled. Claims 25-28 have been added based on the disclosure at page 19, line 8-9 and the compound recited in claim 16.

Entry of the above amendment is respectfully requested.

**Obviousness Rejection**

Claims 9, 14-16 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnstone (US 6,262,105 B1) in view of Skuballa et al. (US 4,088,775).

In response, Applicants note initially that although claims 1, 5 and 9 of Johnstone cover a compound in which R<sub>2</sub> is H, i.e., a PGF analogue whose omega chain does not have any ring moiety, all the compounds listed in Table 1 of Johnstone have a ring moiety on their omega chain. In Johnstone, only latanoprost was used in the working examples to examine the effect on hair growth. None of the other compounds was examined, and the art cannot predict the effect of the other compounds such as those having H as R<sub>2</sub> from Johnstone.

According to the Examiner, Sukuballa suggests that any effect of any prostaglandin derivative can be enhanced by replacing the hydroxy group at the 15 position with ketal. Applicants disagree, as discussed further below. However, Applicants consider that assuming the artisan was motivated to combine Johnstone with Sukuballa, that artisan would try to change 15-OH of latanoprost or PG derivatives shown in Table 1 of Johnstone with 15-ketal. Applicants

submit that there is no suggestion in Johnstone to choose a PG derivative having no ring moiety on the omega chain for promoting hair growth.

Moreover, and importantly, Applicants submit that if one were to combine Johnstone with Skuballa, one would first change the 15-OH of latanoprost (the compound used in Johnstone's working examples) to 15-ketal, and then when one would see that the latanoprost modified to include 15-ketal has a weaker effect than latanoprost itself (as can be seen from the Rule 132 Declaration submitted herewith, as discussed further below), one would not have been motivated to modify Johnstone to arrive at the present invention. Indeed, Applicants submit that the Declaration evidence shows that even substituting 15-keto, which is disclosed in Johnstone itself, in place of 15-OH of latanoprost is not effective, so Applicants submit that this is another reason why one would not have been motivated to substitute 15-ketal, which is not even disclosed in Johnstone, into Johnstone's compound.

In particular, as set forth on page 4 of the Declaration, the Declarant considers that if one were to combine Johnstone with Skuballa, one would first change the 15-OH of latanoprost (the compound used in Johnstone's working examples) to 15-ketal, and then when one would see that the latanoprost modified to include 15-ketal has a weaker effect than latanoprost itself (note the results for latanoprost are based on latanoprost used at 0.005%), one would not have been motivated to modify Johnstone to arrive at the present invention. Indeed, the Declarant states that the evidence set forth in the Declaration shows that even substituting 15-keto, which is disclosed in Johnstone itself, in place of 15-OH of latanoprost is not effective, so this is another reason why one would not have been motivated to substitute 15-ketal, which is not even disclosed in Johnstone, into Johnstone's compound.

Thus, the Declarant concludes on page 5 of the Declaration that in view of the evidence set forth in the Declaration and the evidence of record, the present invention provides unexpectedly superior results.

Also, in view of the Examiner's comments in the sentence bridging pages 6-7 in the Office Action, Applicants have added dependent claims reciting a concentration range such as 0.001-0.1% of the active ingredient based on the disclosure at page 19, lines 8-9 in the specification. In this regard, Applicants submit that the unexpected superiority of the present invention is adequately supported by all the Declaration evidence, as well as the experimental evidence in the specification (see, e.g., Compound A on page 31 in the specification).

Further in this regard, Applicants submit that the Examiner has not adequately considered the argument that increased hair growth *without the side effect of decreasing IOP* is an unexpectedly superior effect. While the Examiner indicates on page 8 of the Office Action that the effect of reducing IOP may not deter one skilled in the art to use the compounds since Johnstone apparently teaches that these compounds are effective in growing hair even with this effect, such is not the point of Applicants' argument. Rather, Applicants' argument is that the present invention, which increases hair growth without decreasing IOP, is superior to Johnstone's invention, in which hair growth is increased but IOP is decreased. While the Examiner indicates that sometimes side effects are tolerated because of the usefulness of the treatment, Applicants submit that it is better if side effects can be avoided in the first place while still having a useful treatment. Also, while the Examiner indicates that reduced IOP is useful in the population of patients that have glaucoma (see Johnstone, column 3, lines 50-56), Applicants submit that it is not useful in the population of patients that do not have glaucoma. Finally with respect to the Examiner's indication on page 8 of the Office Action that Applicants' invention is

not limited to eyelash growth, Applicants wish to point out that claim 24 and claim 26-28 depending on claim 24 are specifically directed to eyelash growth.

Thus, Applicants submit that the present invention is not obvious over the cited art, and withdrawal of this rejection is respectfully requested.

### Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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